UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,976	04/16/2001	David B. Mount	1242/26/2	3961

25297 7590 03/26/2003

JENKINS & WILSON, PA
3100 TOWER BLVD
SUITE 1400
DURHAM, NC 27707

EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,976	MOUNT ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 58, drawn to an isolated KCC3 potassium-chloride cotransporter polypeptide, classified in class 530, subclass 350.

II. Claims 4-6, 77-78, drawn to an isolated anti-KCC3 antibody, classified in class 530, subclass 387.1.

III. Claims 7-13, 59, drawn to an isolated nucleic acid encoding a KCC3 polypeptide, classified in class 536, subclass 23.1.

IV. Claims 14-17, 58, drawn to an isolated KCC4 potassium-chloride cotransporter polypeptide, classified in class 530, subclass 350.

V. Claims 18-20, 77-78, drawn to an isolated anti-KCC4 antibody, classified in class 530, subclass 387.1.

VI. Claims 21-28, 59, drawn to an isolated nucleic acid encoding a KCC3 polypeptide, classified in class 536, subclass 23.1.

VII. Claims 29-33, 58, drawn to an isolated KCC2 potassium-chloride cotransporter polypeptide, classified in class 530, subclass 350.

VIII. Claims 34-36, 77-78, drawn to an isolated anti-KCC2 antibody, classified in class 530, subclass 387.1.

IX. Claims 37-43, 59, drawn to an isolated nucleic acid encoding a KCC2 polypeptide, classified in class 536, subclass 23.1.

X. Claim 44, drawn to a transgenic non-human animal having incorporated into its genome a nucleic acid molecule encoding a biologically active KCC2, KCC3, or KCC4 polypeptide, classified in class 800, subclass 8.

XI. Claims 45-46, drawn to an isolated KKC2, KCC3, or KCC4 genomic DNA molecule, classified in class 536, subclass 23.1.

XII. Claims 47-49, drawn to a method of producing an antibody immunoreactive with a KCC polypeptide, classified in class 435, subclass 4.

XIII. Claim 50, drawn to a method of detecting a potassium-chloride cotransporter polypeptide comprising immunoreacting the polypeptide with an antibody, classified in class 435, subclass 7.1.

XIV. Claim 51, drawn to a method of detecting a nucleic acid molecule, classified in class 435, subclass 6.

XV. Claims 52-57, drawn to an assay kit for detecting the presence of potassium-chloride cotransporter polypeptide, wherein the kit comprises numerous antibodies, classified in class 530, subclass 387.1.

XVI. Claims 60-63, drawn to a method to determine the presence or absence of a mutation said method comprising the step of analyzing a nucleic acid sample, classified in class 435, subclass 6.

XVII. Claims 60-63, drawn to a method to determine the presence or absence of a mutation said method comprising the step of analyzing a protein sample, classified in class 435, subclass 7.1.

XVIII. Claims 64-66, drawn to a method of screening candidate substances for an ability to modulate potassium-chloride transporter biological activity, classified in class 435, subclass 4.

XIX. Claim 67, drawn to a recombinant cell line, classified in class 435, subclass 325.

XX. Claims 68-69, drawn to a method of identifying a candidate compound as a modulator of potassium-chloride cotransporter biological activity, classified in class 435, subclass 6.

XXI. Claims 70-76, drawn to a method of modulating potassium-chloride cotransporter biological activity in a vertebrate subject comprising administering an effective amount of a substance, classification dependent upon structure of substance.

XXII. Claims 77-78, drawn to a pharmaceutical composition comprising a therapeutically effective amount of a polypeptide modulator of biological activity, classified in class 530, subclass 350.

XXIII. Claims 79-83, drawn to a method for modulating potassium-chloride cotransporter comprising introducing to a tissue in a subject a construct comprising a nucleic acid sequence, classified in class 435, subclass 6.

XXIV. Claims 84-87, drawn to a kit for detecting a polymorphism in a KCC gene comprising a reagent for detecting a polymorphism, classification dependent upon structure of reagent.

XXV. Claim 88, drawn to a transgenic non-human animal having modified or deleted from its genome a nucleic acid molecule encoding a biologically active KCC polypeptide, classified in class 800, subclass 8.

XXVI. Claims 89-90, drawn to an isolated Xenopus KCC potassium-chloride cotransporter polypeptide, classified in class 530, subclass 350.

XXVII. Claims 91-93, drawn to an isolated Xenopus anti-KCC antibody, classified in class 530, subclass 387.1.

XXVIII. Claims 94-100, drawn to an isolated nucleic acid molecule encoding a Xenopus KCC4 polypeptide, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-XI, XV, XIX, XXII, XXIV-XXVIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions XII-XIV, XVI-XVIII, XXI, and XXIII are different methods because they require different ingredients, process steps, and endpoints. Groups XII-XIV, XVI-XVIII, XX-XXI, and XXIII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention XII requires search and consideration of transfecting a host cell with a nucleic acid molecule, recovering the polypeptide, and preparing an antibody to the polypeptide, which is not required by the other inventions. Invention XIII requires search and consideration detecting a potassium-chloride cotransporter

polypeptide by immunoreacting a polypeptide with an antibody to form a conjugate and detecting the conjugate, which is not required by the other inventions. Invention XIV requires search and consideration of detecting a nucleic acid molecule in a sample by hybridizing a nucleic acid molecule to the nucleic acid material in the sample and detecting the hybridization complex, which is not required by the other inventions. Invention XVI requires search and consideration of analyzing a nucleic acid sample for the presence of a mutation in a human KCC gene, which is not required by the other inventions. Invention XVII requires search and consideration of analyzing a protein sample for the presence of a mutation in a human KCC gene, which is not required by the other inventions. Invention XVIII requires search and consideration of screening substances for an ability to modulate potassium-chloride cotransporter biological activity by administering a candidate substance to a test sample and measuring the interaction, which is not required by the other inventions. Invention XX requires search and consideration of identifying a candidate compound as a modulator by contacting a cell sample, which contains a DNA construct, with a candidate compound and evaluating the signal produced compared to control, which is not required by the other inventions. Invention XXI requires search and consideration of efficacy of therapy of administration of a substance capable of modulating the activity of a KCC polypeptide, which is not required by the other inventions. Invention XXIII requires search and consideration of modulating potassium-chloride cotransport by introducing into a tissue a construct comprising a nucleic acid sequence encoding a KCC gene product, which is not required by the other inventions.

c. Inventions I/III-IV/VI-VII/IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the products claimed can be used in materially processes, such as in diagnostic or therapeutic assays.

d. Inventions III/VI/IX and XIV/XVI/XX/XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products claimed can be used in materially different processes, such as for protein production or gene therapy.

e. Inventions I/IV/VII and XVII/XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products claimed can be used in materially different processes, such as use as antigen for the production of antibodies.

f. Inventions I/IV/VII and XIII/XIV/XVI/XX-XXI/XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I/IV/VII and XIII/XIV/XVI/XX-XXI/XXIII are unrelated product and methods, wherein each is not required, one for another. For example, the polypeptides of Inventions I/IV/VII cannot be used together with the claimed methods of Inventions XIII/XIV/XVI/XX-XXI/XXIII because these inventions do not recite the use or production of the polypeptides of Inventions I/IV/VII.

g. Inventions II/V/VIII and XII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups II/V/VIII and XII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated product and methods, wherein each is not required, one for another. For example, the antibodies of Inventions II/V/VIII cannot be used together with the claimed methods of Inventions XII-XIV/XVI-XVIII/XX-XXI/XXIII because these inventions do not recite the use or production of the antibodies of Inventions II/V/VIII.

h. Inventions III/VI/IX and XIII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups III/VI/IX and XIII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated product and methods, wherein each is not required, one for another. For example, the nucleic acid molecules of Inventions III/VI/IX cannot be used together with the claimed methods of Inventions XIII-XIV/XVI-XVIII/XX-XXI/XXIII because these inventions do not recite the use or production of the nucleic acid molecules of Inventions III/VI/IX.

i. Inventions V/VIII and XII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups V/VIII and XII-XIV/XVI-XVIII/XX-XXI/XXIII are unrelated product and methods, wherein each is not required, one for another. For example, the polypeptides of Inventions I/IV/VII cannot be used together with the claimed methods of Inventions XIII/XIV/XVI/XX-XXI/XXIII because these

inventions do not recite the use or production of the polypeptides of Inventions I/IV/VII.

j. Inventions X/XI/XV/XIX/XXII/XIV-XVIII and XII-XIV/XVI-XVIII/XXI/XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XI/XV/XIX/XXII/XIV-XVIII and XII-XIV/XVI-XVIII/XXI/XXIII are unrelated product and methods, wherein each is not required, one for another. For example, the products of Inventions XI/XV/XIX/XXII/XIV-XVIII cannot be used together with the claimed methods of Inventions XII-XIV/XVI-XVIII/XXI/XXIII because these inventions do not recite the use or production of the claimed products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and divergent subject matter, restriction for examination purposes as indicated is proper.

2. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

The inventions as they pertain to each of the amino acid and nucleic acid sequences of SEQ ID NOS: 1-129, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

k. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 1-129 is a unique amino sequence or nucleic acid sequence, requiring a

ID NOS: 1-129 is a unique amino sequence or nucleic acid sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different separate search requirements and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must select one from Groups I-XXVIII. Applicant must also select one amino acid sequence and one nucleic acid sequence from SEQ ID NOs: 1-129. Applicant is advised that neither I-XXVIII nor the amino acid/nucleic acid groups are species election requirements; rather, each of I-XXVIII and amino acid sequence/nucleic acid sequence is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
March 23, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600